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Dec 21, 1999

US-PAT-NO: 6004582

DOCUMENT-IDENTIFIER: US 6004582 A

TITLE: Multi-layered osmotic device

DATE-ISSUED: December 21, 1999

INVENTOR-INFORMATION:

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US-CL-CURRENT: 424/473, 424/468, 424/472, 424/474, 424/475, 424/476, 424/479, 424/482

CLAIMS:

We claim:

1. An improved multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the drug;

b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;

c) an inert, completely erodible water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the wall; and

d) an external coat comprising a second active agent for immediate release of the drug, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the

first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

2. An osmotic device according to claim 1 wherein the compressed core further comprises poly(vinylpyrrolidone).

3. An osmotic device according to claim 1 wherein the semipermeable membrane consists essentially of cellulose acetate and poly(ethylene glycol).

4. An osmotic device according to claim 1 wherein the external coat comprises poly(vinylpyrrolidone) and poly(ethylene glycol).

5. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent.

6. An osmotic device according to claim 1 wherein the first active agent in the core comprises a therapeutic agent.

7. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a therapeutic agent.

8. An osmotic device according to claim 7 wherein the first and second active agents are the same.

9. An osmotic device according to claim 8 wherein the first and second active agents are theophylline.

10. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a different therapeutic agent.

11. An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is loratadine.

12. An osmotic device according to claim 10 wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.

13. An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is astemizole.

14. An osmotic device according to claim 10 wherein the first active agent is diltiazem and the second active agent is enalapril.

15. An osmotic device according to claim 1, wherein the one or more environments of use comprises a first environment of use and a different second environment of use.

16. An osmotic device according to claim 15, wherein the first environment of use is the gastric region and the second environment of use is farther down the gastrointestinal tract of a mammal.

17. An osmotic device according to claim 1, wherein the first and second active agents are released into the same environment of use.

18. An osmotic device according to claim 1, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.

19. An osmotic device according to claim 1, wherein at least a portion of the polymer coat dissolves or erodes in fluid present in an environment of use after the external coat has at least partially dissolved in an environment of use.

20. An osmotic device according to claim 1, wherein the polymer coat is one or more of soluble in the same environment of use in which the external coat is soluble, and soluble in the same environment of use in which the core is soluble.

21. An osmotic device according to claim 1, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and

cellulose-ester-ether.

22. An osmotic device according to claim 1, wherein the external coat further comprises poly(vinylpyrrolidone).

23. An osmotic device according to claim 1, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).

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FIELD-OF-SEARCH: 424/468, 424/472, 424/473, 424/476, 424/479, 424/482, 424/474, 424/475

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

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	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
<input type="checkbox"/>	<u>4014334</u>	March 1977	Theeuwes et al.	128/260
<input type="checkbox"/>	<u>4335099</u>	June 1982	Funakoshi et al.	424/32
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ART-UNIT: 165

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ABSTRACT:

The present invention provides a simple and improved multi-layered osmotic device (1) that is capable of delivering a first active agent in an outer lamina (2) to one environment of use and a second active agent in the core (5) to another environment of use. Particular embodiments of the invention provide osmotic devices in which the first and second active agents are similar or dissimilar. An erodible polymer coat (3) between an internal semipermeable membrane (4) and a second active agent-containing external coat (2) comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer. This particular erodible polymer results in an improved multi-layered osmotic device possessing advantages over related devices known in the art. The active agent in the core (5) is delivered through a pore (6) containing an erodible plug (7). The osmotic device (1) can be coated by a final finish coat (8).

23 Claims, 2 Drawing figures